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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,697	12/23/1999	WALID NAJIB ABOUL-HOSN	AMED056	6483

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A-MED SYSTEMS INC  
INTELLECTUAL PROPERTY  
2491 BOATMAN AVENUE  
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EXAMINER

BIANCO, PATRICIA

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 11/04/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/470,697	ABOUL-HOSN ET AL.
	Examiner Patricia M Bianco	Art Unit 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on Election filed 8/14/02.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 2,7,12,15 and 16 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3-6,8-11,13 and 14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 December 1999 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <i>Detailed Action</i> .      |

## DETAILED ACTION

### ***Election/Restrictions***

1. Applicant's election of Species H in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1, 3-6, 8-11, 13 & 14 are readable thereon and have been examined on the merits.
  
2. Claims 2, 7, 12, 15 & 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

### ***Drawings***

3. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.
  
4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **first and second interior flow paths** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. With respect to the elected Species H, Figures 16-19, the drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **deformable flexible wire** and **the pump** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

- ✓ • 300 is not shown in figure 22 as disclosed on pg. 28, line 15
- ✓ • 241 is not shown in figure 23 as disclosed on pg. 26, lines 21-23 & pg. 28, line 23)
- ✓ • 641 is not shown in figures 24 & 25 as disclosed on pg. 30, lines 23 & 26

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description:

- 214 shown on figure 23
- 611 shown on figures 24 & 25
- 79 shown on figure 26
- 720 and 730 shown on figures 26 & 27
- 541, 590 and 591 shown on figures 28-30

A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

8. The drawings are objected to because of the following minor informalities:

figures 26 and 27 show cross-section markings ( □ ), however, does not show a cross-section of the cannula system. Should there be a number indicating a figure which shows the cross-sectional views about this marking?

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

9. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "230" and "242" have both been used to designate an inflow port. A proposed drawing correction or corrected drawings are required in reply

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to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Specification***

10. The use of the trademark **NITINOL™** has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

11. The disclosure is objected to because of the following informalities:

- In the brief description of the drawings, it states that figure 25 is a cross-section of figure 9 across lines 25-25. The drawing shows that it is a cross-section of figure 24
  - In the brief description of the drawings, it states that figures 18 & 19 are cross-section of and a side-sectional view figure 1. The drawing shows that it appears to be cross-sectional and side-section views of figure 16.
  - The claims are not on a separate sheet at the end of the disclosure. The guidelines for the preferred layout for the specification of a utility application require that the claim or claims commence on a separate sheet
- Appropriate correction is required.

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12. The attempt to incorporate subject matter into this application by reference to the variable volume rotor and diaphragm of Application Serial Number **08/933,566** (see page 20 of the specification) is improper because applicant is incorporating "essential material." "Essential material" is defined as that which is necessary to describe the claimed invention, provide an enabling disclosure of the claimed invention or describe the best mode of the claimed invention. In this case, the essential material of the claimed invention disclosed in the incorporated reference application, is the further limitations defining the combination of the pump, the first flow path and the second flow path having a combined priming volume external of the heart not greater than about 1000 ml, or not greater than about 30 ml, or not greater than about 10 ml as set forth in claims 3-5.

*Ex Nc*

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1 & 3-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant claims "a cannula body having a distal end....and including first and second interior flow paths" in claim 1. The written description does not provide an adequate description of first and second flow paths, where one of the first and second flow paths each communicates

with a conduit or a port. While the terms "first and second flow paths" are briefly mentioned in the Summary of the Invention, said paths are not mentioned in the detailed description of the invention and the drawings do not show a structural feature indicated to be said first and second flow paths.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1, 3, & 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims "a cannula body having a distal end....and including first and second interior flow paths" in claim 1. It is unclear in view of the specification and drawings what Applicant is claiming by the language "first and second interior flow paths" since the term is not clearly shown in the specification. Applicant does state on page 24, lines 22-24 that the cannula of the elected embodiment may have other lumens besides the main lumen. Would the multiple lumens in the embodiment of figures 16-19 be equivalent to first and second flow paths? Or does the embodiment shown in non-elected embodiments of figures 1-15, comprising a cannula system that is made up of an inner cannula and an outer cannula, each having a single lumen wherein one cannula is inside the other, define the first and second interior flow paths? As best understood by the examiner, the lumen of the tubular portion (220) and main lumen (211) of the cannula system of the elected

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embodiment (figures 16-19) are equivalent to the first and second interior flow paths of the system required by the claims.

- ✓ 15. Claim 3 recites the limitation "the pump" in line 2. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 1, 8-11 & 13 are rejected under 35 U.S.C. 102(e) as being anticipated by DeVries (6,042,576). DeVries discloses a cannula system that may be connected to an extra-corporeal bypass system. The cannula system has a tubular body (42) made of attaching two pieces, the distal end (56) of a first tube is attached to the proximal portion (54) of a second tube (see col. 4, lines 41-46). The two tubes inherently define individual lumens. As best understood by the examiner, the combined lumens of the

two tubular portions of the cannula system is equivalent to the first and second interior flow paths of the system required by the claims. The extreme distal end has an opening (46) communicating with a lumen equivalent to applicant's port. The distal portion of the cannula has a bend or apex (48). With respect to claims 9-11, DeVries meets these limitations of the bend to be an angle between 0 and 360 degrees relative to the main axis since it is shown in figures 3 & 4 to be approximately 90 degrees or may be angled to either an acute or obtuse angle (col. 3, lines 49-55).

17. Claims 1, 3-6, 8-11, & 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Aboul-Hosn (6,083,260). Aboul-Hosn discloses a cannula system for transporting body fluids into and/or out of a vessel or heart chamber. The device comprises an outer cannula (30) having an inner cannula (20) disposed within its lumen. The outer cannula and inner cannula both have individual lumens that are seen to be equivalent to "the first and second fluid flow paths" of applicant's invention. The outer cannula has an opening just proximal to the balloon, which is seen to be equivalent to Applicant's claimed "port," to allow fluid to exit its lumen or flow path. The inner cannula may have a permanent bend formed in an angle of 10 to 120 degrees (col. 7, lines 30-34) and the conduit may be reinforced with a material to provide sufficient stiffness to resist collapsing (col. 7, lines 40-44). Aboul-Hosn also discloses a reverse flow pump (50) that is connected to the outer cannula (30) (see col. 15, lines 9-35). With respect to the priming volume external of the heart not greater than about 1000 ml, or not greater than about 30 ml, or not greater than about 10 ml as set forth in claims 3-5, the

apparatus of Aboul-Hosn is the device incorporated by reference by applicant in the instant application and therefore inherently has a combined volume as required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 3-6 & 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('576) in view of Aboul-Hosn ('260). DeVries discloses the invention substantially as claimed, see rejection supra. DeVries, however, fails to disclose specifically the priming volume external of the heart not greater than about 1000 ml, or not greater than about 30 ml, or not greater than about 10 ml as set forth in claims 3-5 ,

a pump attached to the cannula as set forth in claim 6, and including a deformable flexible wire within the body to form the two-dimensional configuration as set forth in claim 14.

Aboul-Hosn discloses a cannula system for transporting body fluids into and/or out of a vessel or heart chamber wherein the system includes a cannula having a pump attached to a lumen and a bend in the distal portion of the cannula. The bend is formed in an angle of 10 to 120 degrees, thereby being a two-dimensional configuration. Since Aboul-Hosn teaches that the system may be reinforced with a material to provide sufficient stiffness to resist collapsing, such as steel wire (col. 7, lines 40-44), it would have been obvious to include the reinforcing wire in the bend portion. Aboul-Hosn also discloses a reverse flow pump (50) that is connected to the outer cannula (30) (see col. 15, lines 9-35). The apparatus of Aboul-Hosn is the device incorporated by reference by applicant in the instant application. With respect to the priming volume external of the heart not greater than about 1000 ml, or not greater than about 30 ml, or not greater than about 10 ml as set forth in claims 3-5, the apparatus of Aboul-Hosn inherently has a combined volume as required.

At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the cannula system and bend of DeVries to include a reinforcing wire since it is well known in the art to provide sufficient stiffness to resist collapsing while inserted into the vasculature of a patient during use. Also, DeVries discloses that the cannula may be connected to a bypass system, wherein said bypass system will inherently include a pump. Therefore, at the time of the invention it would have also

been obvious to one having ordinary skill in the art to modify the pump and the cannula to be sized as taught by Aboul-Hosn to provide a priming volume external of the heart not greater than about 1000 ml, or not greater than about 30 ml, or not greater than about 10 ml, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

- ✓ 19. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn ('260). Aboul-Hosn discloses the invention substantially as claimed, see rejection supra. Aboul-Hosn, however, fails to disclose specifically including a deformable flexible wire within the body to form the two-dimensional configuration. Since Aboul-Hosn teaches that the system may be reinforced with a material to provide sufficient stiffness to resist collapsing, such as steel wire (col. 7, lines 40-44), it would have been obvious to include the reinforcing wire in the bend portion. At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the cannula system and bend of DeVries to include a reinforcing wire since it is well known in the art to provide sufficient stiffness to resist collapsing while inserted into the vasculature of a patient during use.

### ***Conclusion***

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Phillips ('856) discloses a method of ventricular assist using a

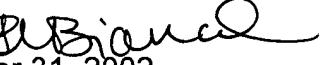
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flexible cannula and pump system. Caro et al. ('516) discloses a flexible cannula having an angled bend at the distal end. Mangosong et al. ('713) disclose a slideable cannula system wherein one of the slideable cannulas has a bend at the distal end. Giannoble ('911) discloses an analogous cannula having a helical support member that may be bent at the distal end.

21. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco  
Patent Examiner  
Art Unit 3762

pmb   
October 31, 2002